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 June 20, 1974

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ORC VCM Task Force Meeting on OSHA Hearings
June 18, 1974

The morning meeting with OSHA representatives included

Mr. Lewis Cox - Staff Assistant to Mr. Stender;
 Mr. James Kallenborn - of John Plummer's Research Office
 for Planning, Evaluation and Review;
 Jess Hill and four young OSHA staff people, preparing to
 digest the testimony and prepare the first draft of the
 final standard;
 ORC representatives from RMA, Uniroyal, Firestone,
 Goodyear, Union Carbide, duPont, Tenneco and American Can.

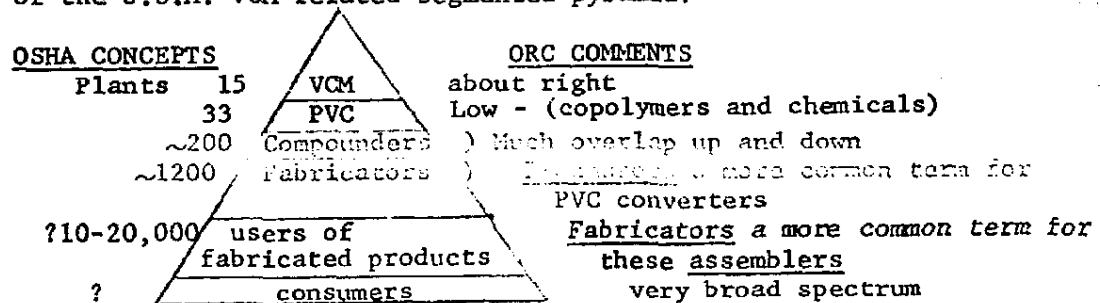
a) Mr. Cox assured the group that Mr. Stender was concerned about the serious economic impact of the permanent standard regulations on vinyl chloride. He read Section 6 B (5) of OSHA/70 on toxic materials, emphasizing the need to employ the best available evidence based on research in arriving at feasible standards that would insure protection of the employee during his working life and that these should be based on objective criteria to meet the performance desired. He said, Mr. Kallenborn and the research staff have been requested to prepare an impact statement to guide final standard promulgation.

b) Mr. Kallenborn summarized the current OSHA timetable:

June 10 - Public comments - passed
 June 17 - Requests for participation in hearings - passed
 June 25-28 - Oral hearings and written testimony
 ~ July 9 - staff work on draft commences
 open - closure of written testimony
 Oct. 5 - Legal time limit on permanent standard promulgation.

He emphasized that, if substantial research projects were underway that would contribute substantive information to help in promulgating a better standard, these should be emphasized at the June 25 hearing, and requests should be made for delays in closing the record or even additional later hearings that might logically postpone the promulgation date.

c) Mr. Kallenborn presented a graphic chart of their current understanding of the U.S.A. VCM related segmented pyramid:



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d) Mr. Kallenborn summarized the current OSHA thinking on essential concepts addressed in the proposed permanent vinyl chloride standard:

1. Engineering
2. Personnel protection
3. Monitoring of personnel exposure
4. Medical surveillance
5. Records of employee exposure and medical surveillance
6. Workers included
7. Regulated areas
8. Exposure levels

It was agreed that these were interrelated and that there might be others. He suggested that industry testimony be addressed to each area, so that the new regulation not be in default by too strong a focus on exposure levels, where everyone is in an area of speculation.

e) Discussions with respect to needed facts to be brought out in oral and written testimony have been summarized by reference to these eight concepts:

General

The major reductions in VCM exposure risks as one goes down the various segments of the pyramid, and, therefore, the differences in required employee protection standards, should be emphasized in several ways - industry segments, job classifications, emergency release risks, complexity of worker mobility constraints (re protective equipment), and time, economics and knowledge feasibility of compliance with various VCM exposure levels - 50 ppm, 20 ppm and "1 ppm $\pm$ 50%".

- (1) Kallenborn defended the basic OSHA policy of placing this as the principle solution to any abatement problem, with worker protection designated as an interim solution. They do not regulate how and recognize different solutions for different industries and plants.

They also recognize timetables and economics to be associated with engineering solutions. They are asking industry through ORC for factual information (questionnaire attached) on economics and technical feasibility status for both engineering and protective equipment (2). ORC has asked for a preliminary response to this request by the first week in July (to be presented anonymously to OSHA office by July 9).

- (2) Protective equipment for personnel needs factual data on worker discomfort, efficiency, worker safety correlated with possible worker risks in various types of differentiated industry segments and job assignments. Testimony could include psychological and medical impacts of 8 hour space suits on workers (but there are some industries such as nickel carbonyl users - Reppe acrylates and oxo alcohols(?) - where 8 hour respirators is reported to be a standard practice). (The subject of impervious suits was not discussed, but facts are obviously needed).

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- (3) Monitoring of workers' breathing zone is OSHA's area of responsibility; work area monitoring is industry's prerogative to efficiently control and correlate. It is important that this distinction be maintained in testimonies. However, the recommended "10 minute" grab sample "ceiling" measurement as a monitoring technique to protect the worker is unrealistic, whatever the exposure level other than "non-detectable" at $1 \text{ ppm} \pm 50\%$. The actual "puff" conditions in PVC polymerization plants was brought out, and therefore the logical importance of a TWA exposure level was emphasized by the industry representatives.

As continuous analyzers are installed in plants, it becomes more apparent that brief "excursions" are far more prevalent than first supposed, based on either ambient air grab samples or personnel monitoring. The potential chaos from trying to freeze a fluid engineering/monitoring interplay in developing a permanent standard at this point in time needs factual testimony.

The precipitous drop from 500 ppm to 50 to "no detectable" at $1 \text{ ppm} \pm 50\%$ in a matter of weeks is traumatic to many VCM/PVC companies and a new era to PVC processors and fabricators. Discriminatory work area monitoring equipment is not available for immediate delivery, and reliable monitoring procedures are not feasible for vinyl chloride concentrations much less than 10 ppm where interfering substances require definitive proof after gaschromatographic separation. Further, there are insufficient trained personnel to calibrate and maintain such equipment in any but the largest companies. Further, the time delays inherent in sample shipment to central laboratories for discriminatory analysis makes personnel monitoring inadequate for control of emissions and exposure to workers.

(4) Medical Surveillance

So far no medical association has responded in the call for public response (June 10) to the proposed regulations in this area. Industry medical people at the meeting pointed out

- (a) the data to be gathered are not indicative of liver cancer, nor of any vinyl chloride or occupation-related response. They are the best data gathering research tools now available to indicate the state of the workers' health and possibly indicative of liver function.
- (b) There is no criterion as to the quality of the medical practitioner required for interpretation of the tests and an implication of medical practice by distant regulation, not the doctor/patient relationship required for accepted medical practice.
- (c) There is value in having a state of the developing art test protocol available to companies for their medical officers. This should not be part of the regulations but referenced and recommendations of means for qualified industry and Government medical people to update it on a regular basis.

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- (d) The concept of the 14 carcinogens regulatory language is generally acceptable to the industry's medical people for this area.
- (e) Prof. Maltoni's comments on the questionable value of physical examinations and present tests as predictive for occupational health and cancer in particular should be in the record:

Excerpta Medica Amsterdam report of proceedings
of the Second Symposium on Cancer Detection and
Prevention, held April 9-12, 1973

Maltoni - Occupational Carcinogenesis
Pgs. 1-8, ISBN 90 21902 281

He recommends a research program on an international level
based on periodic examinations by qualified medical research
people.

(5) Records

There was no discussion, but Kallenborn said - if you have any points to make, be sure to include them separately from under the other seven subjects. (poor records are the easiest for an inspector to criticize and review).

(6) Workers to be included

These should be categorized by industry as to average exposure levels and probability of emergency exposures. For example, office workers should not have the same control requirements as laboratory, maintenance or production as to work practices, etc. This should be correlated with comments on (7).

(7) Regulated Areas

The industry should comment on the need for differentiation of these areas by industries, types of manufacturing operations, and by service areas within plants. This should be related to types of job assignments in (6), and with relative exposure levels and risks of sudden VCM releases. These, in turn, should be related back to (1) as to engineering improvement feasibility and cost, as well as (2) the protective equipment feasibility, hazard and necessity.

(8) The allowable exposure level had its usual high degree of discussion in spite of Kallenborn's plea to avoid arguing the imponderable "safe" level without adequate information. Some additional viewpoints that were expressed include:

- (a) If the level is reasonable and low, it eliminates many of the problems related to (1) and (7).

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- (b) It does provide the criterion for performance and gives management the flexibility as to means of achieving it.
- (c) The concepts that engineering solutions are the "ultimate solution" and personnel protective equipment are "temporary" is built into OSHA regulations and have stood court tests.
- (d) Human data does not support the existence of a problem at 50 ppm and, therefore, the arbitrary imposition of "no detectable" is unreasonable and unnecessary.
- (e) If one assumes early PVC/VCM human worker TWA exposures to over 1000 ppm for 10 years = over 10,000 ppm man years, goals of

<u>1000 ppm man years =</u>	<u>500 ppm man years =</u>
50 x 20 yrs	50 x 10 yrs
25 x 40 yrs	25 x 20 yrs
10 x 100 yrs	10 x 50 yrs
5 x 200 yrs	5 x 100 yrs
1 x 1000 yrs	1 x 500 yrs

Diagnosed angiosarcoma worker risk, assuming 100% more to come than now identified in the older plants, is between 1% and 2%.

This inadequate data could lead to the speculation that "undetectable" as defined in the proposed standard is unnecessarily conservative, as compared with the known and unregulated causes of cancer with much larger population exposure, such as cigarette smoking.

ORC Testimony

In the afternoon session without OSHA representatives, Wayne Brooks said the ORC testimony would be re-written to better fit industry and OSHA mutual objectives of:

- (1) differentiating processors and fabricators from "PVC" producers (VCM converters) (and from VCM producers).

ORC pleaded with ORC companies to submit available information in response to OSHA's questionnaire by week of July 2-5. Anonymity would be assured in written submission to OSHA.

Concern was expressed on misuse of the information by OSHA.

Concern was expressed that if we did not document such points, for further documentation with time, that a "legal reopening" would be far more difficult.

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- (2) the unreasonable nature of "no detectable" and its obvious contradictions with all of the other regulations.

The legal necessity of correlating comments on exposures to the employee for OSHA jurisdiction. Work area monitoring is only a means for implementing the regulation and, therefore, not subject to OSHA citation. The TWA concept is not conducive to OSHA inspection and could prove onerous to industry in demonstrating compliance. Alternatively, the sporadic nature of VCM emissions in plant operation, as demonstrated by continuous monitoring, makes the proposed grab sample concept for ceilings illogical - especially at low concentrations- and entirely inappropriate for timely and responsible protection of the worker.

- (3) Medical surveillance and administrative response procedures need change from the NIOSH recommendations.
- a. It needs industry differentiation.
 - b. This is a new area of research, and we must not freeze protocols.
 - c. Regulations implies practice of medicine from Washington.
 - d. Response procedures ignore differences between individuals which can best be handled by a qualified physician.
 - e. Guidelines and registry system idea is good - as an open ended communications and instrument, subject to annual review by qualified industry-Government medical representatives, but not part of the regulations.
 - f. The general language of the 14 carcinogens regulation is much more meaningful and appropriate for a medical problem as recently discovered as VCM.
- (4) The basis for the present proposed standard of "no detectable" was stated to be the Industrial Bio-Test data on mouse exposure at 50 ppm. This is inadequate, especially when rats, "a much better test animal than mice" according to Professor Maltoni, died with cancer at very old ages at 50 ppm exposure levels.
- (5) Flexibility of time schedules for setting and achieving goals for reasonable and low levels of exposure is essential.
- a. There are many R&D projects underway towards setting better "socially acceptable risk" levels for vinyl chloride exposure:

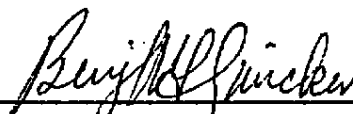
Europeans' epidemiological studies
ORC mortality study
MCA toxicology research projects
European toxicology research projects
U. S. Government epidemiology surveys
BFG medical research - Univ. Louisville
Firestone and Uniroyal studies (Univ. North Carolina)

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- b. There are still engineering R&D programs to be completed, to find technologically feasible ways of reducing emission levels in existing plants. New plant designs for "no emission" levels are even further away. Equipment procurement and construction timetables are escalating unbelievably in this energy crunch period.
- c. Feasible analytical methods are not adequate and sufficient equipment and manpower is not now available to implement an effective discriminatory vinyl chloride monomer monitoring (work area and personnel) at levels below 10 ppm for the VCM/PVC industry alone, omitting the processors and fabricators.

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